CLAIMS

1. A topical nanoparticulate spironolactone formulation comprising nanoparticles having a mean diameter, measured by photon correlation spectroscopy, in the range of from about 300nm to about 900nm incorporated into a crystalline network system comprising a dispersion of solid crystals of polar lipids, said lipids exposing their hydrophilic side outwards and their hydrophobic side inwards towards the spironolactone nanoparticles.

2. A formulation according to claim 1 comprising nanoparticles having a mean diameter, measured by photon correlation spectroscopy, in the range of from about 400nm to about 600nm.

3. A formulation according to claims 1 or 2 wherein the lipid has a crystallisation temperature of between 20°C and 100°C

4. A formulation according to claims 1 to 3 wherein the lipid crystals are β crystals of a monoglyceride of a fatty acid having 12-18 carbon atoms, or ascorbic, phosphate or lactic esters of fatty acids or of monoglycerol ethers or mixtures thereof.

5. A formulation according to claim 4 wherein the monoglyceride is 1-monolaurin, 1-monomyristin, 1-monopalmitin or 1-monostearin or a mixture of two or more of these.

6. A formulation according to claims 1 to 5 wherein the wherein crystalline network structures of polar lipids are formed within a polar liquid.

7. A formulation according to any of claim 6 wherein the polar liquid is selected from the group comprising water, glycerol, ethylene glycol or propylene glycol or mixtures thereof.

8. A topical nanoparticulate spironolactone formulation according to any of claims 1 to 7 for use in the topical treatment of acne, hirsutism, androgenic alopecia or rosacea.

9. A formulation according to claims 1 to 8 wherein the active drug is incorporated in the form of a nanosuspension.

10. A formulation according to claim 9 wherein the nanosuspension is an aqueous nanosuspension.

11. A formulation according to claim 10 wherein the nanosuspension comprises a stabiliser.

12. A formulation according to claim 11 wherein the stabiliser is sodium docusate.

13. Use of spironolactone nanosuspensions comprising nanoparticles having a mean diameter, measured by photon correlation spectroscopy, in the range of from about 300nm to about 900nm in the manufacture of a medicament for the treatment of a condition responding to anti-androgens.

14 Use according to claim 13 wherein the condition is selected from acne, hirsutism, androgenic alopecia or rosacea.

15. Use according to claims 13 or 14 wherein the medicament is adapted for topical application.

16. Use according to claims 13 to 15 wherein the nanoparticles are incorporated into a cream base.

17. Use according to claim 16 wherein the cream base consists of a crystalline network of monoglycerides in water or other polar liquids.

18. A method of treating a condition responding to anti androgens comprising administering a nanoparticulate spironolactone formulation according to claims 1 to 6 to a patient in need of such treatment.

19. A method according to claim 18 wherein said condition is selected from the group consisting of acne, hirsutism, androgenic alopecia or rosacea.

20. A crystalline network system comprising a dispersion of solid crystals of polar lipids, said lipids exposing their hydrophilic side outwards and their hydrophobic side inwards towards an incorporated substance for use in the topical treatment of acne.

21. A process for the preparation of a topical nanoparticulate spironolactone formulation comprising nanoparticles having a mean diameter, measured by photon correlation spectroscopy, in the range of from 300nm to about 900nm, wherein the process comprises incorporation of a nanosuspension of spironolactone into an aqueous dispersion of solid crystals of polar lipids, said lipids exposing their hydrophilic side outwards and their hydrophobic side inwards towards the spironolactone nanoparticles.